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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT KLEIMAN and JAMES H. BROWN

Appellants

Appeal 2009-005006
Application 09/899,432
Technology Center 1600

Decided[1]: July 22, 2009

Before RICHARD TORCZON, SALLY GARDNER LANE, MICHAEL P. TIERNEY, *Administrative Patent Judges*.

LANE, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

I. STATEMENT OF THE CASE

The appeal, under 35 U.S.C. § 134(a), is from a Final Rejection of Appellants' claims 91-102. Claims 1, 3, 4, 6-13, 15, 16, 18, 19, 21, 22, 24, 25, 27, 28, 30, 31, 33, 34, 36-85, 87, 88, and 90 have been cancelled, while claims 2, 5, 14, 17, 20, 23, 26, 29, 32, 35, 86, and 89 have been withdrawn. (App. Br. 4). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Appellants' claims are directed to methods of treating virus-induced or inflammatory diseases.

The Examiner relied upon the following references.

Name	Number	Date
Katz '794	4,874,794	October 17, 1989
Katz '107	5,070,107	December 3, 1991
Katz '392	5,952,392	September 14, 1999
Sintov	WO 96/02244	February 1, 1996
Arquette	WO 99/20224	April 29, 1999

The Examiner rejected claims 91 and 92 under 35 U.S.C. § 103(a) over Katz '392, Sintov, and Arquette. Appellants did not argue separately for the patentability of any of the rejected claims. We focus on claim 91 as a representative claim. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner rejected claims 93-102 under 35 U.S.C. § 103(a) over Katz '392, Sintov, Arquette, and Katz '794 or Katz '107. Appellants did not argue separately for the patentability of any of the rejected claims. We focus on claim 93 as a representative claim. *See* 37 C.F.R. § 41.37(c)(1)(vii).

II. PRINCIPLES OF LAW

"[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and . . . the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case. Such rebuttal or argument can consist of a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have . . . that the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes . . . , or any other argument or presentation of evidence that is pertinent." *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990) (en banc).

"[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

III. ISSUE

Would those of skill in the art have had reason to administer the claimed combination of long chain monounsaturated alcohols, long chain fatty acid salts, and long chain esters to treat virus-induced diseases?

IV. CLAIM 91

Findings of Fact

1. Appellants' claim 91 recites:

> A method for treating at least one of virus-induced and inflammatory diseases, said method comprising the step of providing a topical composition consisting essentially of:

at least one of
octadecenol,
eicosenol,
docosenol,
tetracosenol and
hexacosenol
in a concentration of from 0.1 to 25 percent by weight of an admixed physiologically active carrier;
at least one salt of a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein:
R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$;
x is at least one of 8, 10, and 12; and
M^+ is a monovalent alkali metal ion; and
at least one mixed ester according to the formula R^2-COO-R^3, wherein:
R^2 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_y$;
y is at least one of 6, 8, 10 and 12; and
R^3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms.

(App. Br. 26; Claims Appx.).

2. Katz '392 teaches that inactivation of viruses can be achieved with unsaturated long chain alcohols having from 14 to 20 carbons. (Katz '392 col. 2, ll. 5-7).

3. Katz '392 teaches the specific unsaturated long chain alcohol "γ-linolenyl alcohol," which is a C18 alcohol with three cis double bonds and is significantly more effective than "a C18 alcohol with one cis double bond . . . ." (Katz '392 col. 2, ll. 7-11).

4. The claimed compound octadecenol is a C18 alcohol with one cis double bond.

5. Appellants do not dispute that the monounsaturated C18 alcohol taught in Katz '392 falls within the scope of the claimed method.

6. Katz '392 teaches administering the long chain alcohol antiviral ingredients at between 1% and 10% by weight of the final composition. (Katz '392 col. 6, ll. 50-52).

7. Katz '392 teaches applying the long chain antiviral ingredients topically, in a physiologically active carrier. (Katz '392 col. 20, ll. 26-42).

8. Katz '392 does not teach combining the monounsaturated long chain alcohols with the long chain fatty acid salts and fatty acid esters claimed.

9. Sintov teaches topical compositions "containing a carboxylic or dicarboxylic acid or a salt thereof as active ingredient therein, in [a] pharmaceutically or cosmetically acceptable carrier" for the prevention and treatment of lesions and sores associated with herpes virus. (Sintov 1).

10. Sintov does not teach C20 or greater fatty acid salts.

11. Arquette teaches that fatty alcohols and waxes can be obtained from the oil in the seeds of the jojoba plant. (Arquette 3, ll. 1-2).

12. Arquette teaches fatty acid esters from jojoba oil that have the formula CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-COO-CH-$(CH_3)_2$, wherein X is 6, 8, 10 and/or 12. (Arquette 4, ll. 12-14).

13. Arquette teaches that these fatty acid esters are effective emollients for pharmaceutical compositions. (Arquette 2, l. 28, through 3, l. 2).

14. Appellants provide two affidavits under 37 C.F.R. § 1.132, one by Robert Kleiman and one by David Ashley, which both report the same experiments and data. (Exhibits 5 and 6).

15. The Kleiman and Ashley affidavits report data comparing the antiviral activity of a compound "K100" with docosanol, a *saturated* C22 alcohol. (Exhibits 5 and 6).

16. The Kleiman and Ashley affidavits identify "K100" only as "the combination of monounsaturated long chain alcohols, jojoba-derived fatty acid salts, and fatty acid esters (specifically, jojoba esters) . . . ." (Exhibits 5 and 6).

17. The Kleiman and Ashley affidavits state that "[w]hen comparing the kill concentrations of the combination of the present invention [K100] and n-docosanol alone, it is shown that the combination of the present invention is approximately 100 times more effective than n-docosanol alone in killing the HSV-1 Strain 6143." (Exhibits 5 and 6).

Analysis

Appellants claim a method of treating a viral or inflammatory disease with a topical composition that consists essentially of (1) at least one of a named long chain alcohol, (2) a salt of a jojoba-derived trans-free fatty acid, and (3) at least one mixed ester. (FF[2] 1). In claim 1, the long chain alcohol is chosen from octadecenol, eicosenol, docosenol, tetracosenol, and hexacosenol.

Katz '392 teaches that monounsaturated long chain alcohols, including the monounsaturated C18 alcohol (FF 3), which Appellants do not dispute falls within the scope of the claimed monounsaturated long chain alcohols (FFs 4 and 5), treat viral infections (FF 2). Katz '392 teaches that

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[2] Finding of Fact.

the long chain alcohol antivirals can be administered topically at between 1% and 10% final weight composition (FF 6) and combined with a physiologically active carrier (FF 7).

Katz '392 does not teach combining a long chain alcohol with other components. (FF 8). Sintov teaches that carboxylic acid salts, which include fatty acid salts, are effective for treating virus-associated diseases. (FF 9), though Sintov does not expressly recite carboxylic acid salts of C20 or greater. In the absence of unexpected results, those of skill in the art would have considered it obvious to use long chain fatty acid salts having the claimed number of carbons to treat viral diseases because Katz '392 teaches that similar C20 carbon compounds are useful for that purpose (FF 2). Given the common utility, those of skill in the art would have had reason to look to C20 or greater fatty acid salts for combination with the monounsaturated long chain alcohols of Katz '392 to treat viral diseases. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 US 398, 417 (2007) ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill implement a predictable variation, § 103 likely bars its patentability."); *see also Dillon*, 919 F.2d at 692-93.

In addition, those of skill in the art would have found it obvious to combine these long chain alcohols and fatty acid salts with the claimed jojoba-derived esters because Arquette teaches that the esters are useful as emollients in pharmaceuticals (FF 11-13).

Appellants argue that neither Katz '392, Sintov, or Arquette teaches the combination of the claimed monounsaturated long chain alcohols and claimed mixed esters with the claimed salts of fatty acids. (App. Br. 15-17

and 21). "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Therefore, Appellants' argument about the deficiencies of each separate reference is not persuasive.

Appellants also argue that Sintov teaches away from combining carboxylic acid salts with other compounds because it states that the disclosed compositions do not require the presence of "any other antiviral agent." (App. Br. 16, quoting Sintov 2). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F3d 551, 553 (Fed. Cir. 1994). Sintov does not discourage those in the art from using other antiviral agents, it merely states the advantage of not *requiring* other antiviral agents. Thus, Sintov does not teach away from the claimed method.

Appellants argue that Sintov teaches away from the claimed method because long chain fatty acid salts with less than 20 carbons have a different solubility in water than the claimed long chain fatty acid salts. (App. Br. 17). Appellants rely on the affidavit of David Ashley (Exhibit 7) as evidence of the difference in solubility between fatty acids of different lengths. We are not persuaded that a difference in water solubility indicates those of skill in the art would not choose C20 or greater long chain fatty acid salts to treat viral infections, as claimed. The claim method is not limited to water as a carrier and Appellants have not persuaded us that an ordinarily skilled artisan would not have been able to find a carrier or solute to deliver the

claimed C20 or greater long chain fatty acid salts. Appellants do not point to characteristics that differ between the long chain carbon compounds of Katz '392 and Sintov that would have discouraged those in the art from using the claimed fatty acid esters in the claimed method.

Appellants argue further that the teaching of Sintov is restricted to a limited number of fatty acid salts, and, thus, excludes the claimed fatty acid salts. (App. Br. 18-19). Appellants point to the use of "consisting of" in Sintov when reciting specific salts. (*Id.*). Sintov, though, expressly provides for topical compositions "containing a carboxylic or dicarboxylic acid or a salt thereof as active ingredient therein, in [a] pharmaceutically or cosmetically acceptable carrier" for the prevention and treatment of lesions and sores associated with herpes virus. (FF 9). That Sintov exemplifies specific carboxylic and dicarboxylic acid salts does not limit what it teaches as prior art. *See In re Mills*, 470 F.2d 649, 651 (CCPA 1972) ("All the disclosures in a reference must be evaluated, including nonpreferred embodiments . . . and a reference is not limited to the disclosure of specific working examples." (citation omitted)).

Finally, Appellants assert that the results of the claimed method are unexpected. (App. Br. 20 and 21-22). Appellants relied on the affidavits of Robert Kleiman and David Ashley as evidence of unexpected results. (FF 14). According to their affidavits, "K100," exhibits a 100 fold increase in antiviral activity over that of docosanol alone. (FF 17). Appellants assert that this increased activity is "surprising" and "synergistic." (App. Br. 21).

"It is well settled 'that objective evidence or non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.'" *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (quoting *In re*

Tiffin, 448 F.2d 791 (CCPA 1971)). Appellants and declarants Kleiman and Ashley indicate only that "K100" is "the combination of monounsaturated long chain alcohols, jojoba-derived fatty acid salts and fatty acid esters (specifically, jojoba esters)" (FF 16; App. Br. 22). Without knowing the specific components of "K100" we cannot know if it is commensurate with the scope of claim 1, or even if it falls within the scope of claim 1. In addition, "when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). Appellants compared the antiviral activity of "K100" with docosanol alone, but docosanol is not a claimed compound. (*See* FF 1). It is not closer to the composition than, for instance, the C18 unsaturated alcohols provided in Katz '392. (*See* FF 3). Thus, we are not persuaded that Appellants have shown unexpected results for the claimed method.

Moreover, Appellants have not provided persuasive evidence that the results with "K100" are "synergistic." The affidavits compare the activity of "K100" to only one compound, docosanol. (FF 15). They do not report the antiviral activity of each component, or other long chain alcohols, recited in claim 91, alone, so that the additive effect can be determined. Without knowing the additive effect, the skilled artisan would not be able to determine if the antiviral activity of "K100" is synergistic.

Appellants have not shown that the Examiner erred in rejection claim 91 under 35 U.S.C. § 103(a) over Katz '392, Sintov, and Arquette.

V. CLAIMS 93-102

Findings of Fact

18. Appellants' claim 93 recites:

> A method for treating viral infections, said method comprising the step of intravenous delivery of a composition consisting essentially of an effective amount of from about 0.1 mg to about 2 gm per 50 kg of body weight of a compound comprising at least one C18 to C24 monounsaturated alcohol in a physiologically active carrier;
>
> at least one salt of a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein:
>
> R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$;
>
> x is at least one of 8, 10, and 12; and
>
> M^+ is a monovalent alkali metal ion; and
>
> at least one mixed ester according to the formula R^2-COO-R^3, wherein:
>
> R^2 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_y$;
>
> y is at least one of 6, 8, 10 and 12; and
>
> R^3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms.

(App. Br. 27, Claims App'x).

19. Katz '794 teaches that C20 to C26 aliphatic alcohols are useful in treating viral infections and inflammatory diseases. (Katz '794 col. 1, ll. 5-7 and col. 3, ll. 63-68).

20. Katz '107 teaches intravenous delivery of C27-C30 aliphatic alcohols to treat viral disease. (Katz '107 col. 3, ll. 57-64).

21. Katz '107 teaches that the aliphatic alcohols can be administered at from 0.1mg/50 kg body weight to 2 gm/50 kg body weight. (Katz '107 col. 4, ll. 45-47).

Analysis

Appellants' claim 93 is similar to claim 91, but instead of reciting specific long chain alcohols, claim 93 recites a C18 to C24 monounsaturated alcohol. (FF 18). In addition, claim 93 requires that the composition be delivered intravenously at between about 0.1 mg to about 2 gm per 50 kg of body weight. (FF 18).

Katz '794 teaches C20 to C26 alcohols that are used to treat viral infections (FF 19), while Katz '107 teaches that long chain alcohols can be used to treat viral disease when delivered intravenously (FF 20) at the claimed dosing ranges (FF 21). We agree with the Examiner that it would have been obvious to those of skill in the art to use C20 to C24 monounsaturated alcohols to treat viral infections by administering them intravenously.

Appellants argue the claimed method produces unexpected results, as evidenced by the Kleiman and Ashley affidavits discussed above. (*See* FFs 14-17). As explained above, these affidavits are not persuasive because they do not show a comparison to the closest prior art and because it is not known if they show results that are synergistic or are commensurate with the scope of the claimed method. Accordingly, we are not persuaded that the claimed method produces unexpected results.

VI. CONCLUSION

Those of skill in the art would have considered it to be obvious to administer the claimed combination of long chain monounsaturated alcohols, long chain fatty acid salts, and long chain esters to treat virus-induced diseases, as claimed.

VII. ORDER

Upon consideration of the record and for the reasons given,

the rejection of claims 91 and 92 under 35 U.S.C. § 103(a) over Katz '392, Sintov, and Arquette is AFFIRMED; and

the rejection of claims 93-102 under 35 U.S.C. § 103(a) over Katz '392, Sintov, Arquette, and Katz '794 or Katz '107 is AFFIRMED.

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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